International Standard

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Health informatics — Requirements for electronic prescriptions

Informatique de santé — Exigences applicables aux prescriptions électroniques

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Foreword

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The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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This document was prepared by Technical Committee ISO/TC 215, *Health informatics,* in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 251, *Health informatics,* in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This second edition cancels and replaces the first edition (ISO 17523:2016), of which it constitutes a minor revision. The changes are as follows:

— introduction of a data model;

— reshuffling of requirements into clauses in line with the data model;

— rephrasing the requirements in well-defined capability statements;

— updating the relationship between other ISO standards and this document such as IDMP.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

Modern healthcare is rapidly advancing and relying on electronic communications. Many countries already have or are in the process of developing electronic systems to contain and distribute personal data regarding healthcare, including the exchange of electronic prescriptions (ePrescriptions). Therefore, it becomes increasingly important to set up a document that can facilitate safe and reliable dispensing and administration of the prescribed product to the patient. Also, since international travelling has become integrated into daily life, it is important that electronic communications regarding prescriptions can somehow be synchronized between prescribers and dispensers in different jurisdictions.

The most important question regarding ePrescriptions is which information is required to be included in the ePrescriptions in order to have exactly the intended medicine dispensed to the patient, including all relevant information with regard to its correct and safe use. This document provides the basic set of information requirements for ePrescriptions.

While the organization of healthcare is national, the development and production of medicinal products on the other hand is truly international. For the identification of medicinal products (IDentification of Medicinal Products, IDMP), five ISO standards are available. This document on ePrescriptions is based on these standards. In addition, the market authorization is strictly legislated in jurisdictional specific directives and laws. Part of this legislation regulates prescribing and dispensing of medicinal products. Information systems in healthcare must be designed so that end-users comply with this legislation (preferably without needing to pay too much attention). An International Standard on ePrescriptions can support the implementation of (international) legislation on medicinal products in health informatics.

The prescription written on paper has a deeply rooted cultural history for both healthcare professionals and patients. Using an ePrescription instead of paper is a change that should be guided to ensure society's trust in healthcare professionals. Requirements for the processing of ePrescriptions can fulfil this need. An example of use in practice of this specification is the following: a general practitioner prescribes a medicinal product for a patient with the aid of an information system and sends the ePrescription to the local pharmacy where the patient picks up the medication a short while thereafter.

The benefit of an International Standard on the requirements of ePrescription is that it can serve as a starting point and reference for all kinds of records and messages related to ePrescriptions, facilitating the communication between stakeholders and information systems.

The intended audience for this document is made up of the developers of standards and information systems, so that, in using their products, end-users (healthcare professionals) comply with legislation, regulations and expectations of society relating to the prescribing and dispensing of medicinal products. Specifically, this document provides a basis for a common understanding of the data elements contained in an ePrescription across legislations.